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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/065,868

11/26/2002

Xue Mei Zhou

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22886

7590

12/15/2006

AFFYMETRIX, INC

ATTN: CHIEF IP COUNSEL, LEGAL DEPT.

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SANTA CLARA, CA 95051

EXAMINER

MILLER, MARINA I

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 12/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/065,868

Applicant(s)

ZHOU ET AL.

Examiner

Marina Miller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4-9, 11-16, 19-23, 25-30, 33-35 and 84-88 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-2, 4-9, 11-16, 19-23, 25-30, 33-35, and 84-88 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date. _____   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicants' submission filed on 9/29/2006 is acknowledged.

Claims 1-2, 4-9, 11-16, 19-23, 25-30, 33-35, and 84-88 are pending.

Claims 3, 10, 17-18, 24, 31-32, and 36-83 are cancelled.

Claims 1-2, 4-9, 11-16, 19-23, 25-30, 33-35, and 84-88 presently are under examination.

Applicants' arguments have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are applied.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Priority***

Applicant's claim for priority under 35 U.S.C. 119(e), 120, and 122 is acknowledged. However, the applications for which priority is claimed fail to provide adequate support under 35 U.S.C. 112 for claims 1-2, 4-9, 11-16, 19-23, 25-30, 33-35, and 84 of the instant application, as set forth in the previous office actions mailed 2/11/2005 and 5/31/2006. The limitations recited in new claims 85-88 are similar to those recited in claims 1-2, 4-9, 11-16, 19-23, 25-30, 33-35, and 84, and therefore the applications for which priority is claimed fail to provide adequate support under 35 U.S.C. 112 for claims 85-88.

As support for the elected claims is not found in the priority applications, priority for the elected claims is granted only to the filing date of the instant application of 11/26/2002.

***Claim Rejections - 35 USC § 101***

***Non-Statutory Subject Matter***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 85-88 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 85 recites a method for providing custom probe array comprising receiving probe set identifiers from a first and second user and producing a probe array having the first and second probe sets on the array. The step of “producing a probe array having the first and second probe sets on the array” may be reasonably interpreted as producing a “virtual array” (*e.g.*, a layout of probes residing in a computer) (*see*, for example, fig. 13-15 of the instant application) because the method does not recite any specific, physical steps of “producing”. Not all processes are statutory under 35 U.S.C. 101. *See* MPEP 2106 (Section IV in particular). To satisfy 101 requirements, the claim must be for a practical application, which can be met if the claimed invention “transforms” an article or physical object to a different state or thing OR the claimed invention otherwise produces a useful, concrete, and tangible result. If claims are directed to abstract ideas (such as mathematical algorithms), natural phenomena, and laws of nature, the claims must be considered as a whole for determining whether an abstract ideas, natural phenomena, or laws of nature has a particular application.

In the instant case, the claimed method does not transform or reduce an article or a physical object (*e.g.*, a probe) to a different stage or thing because the “result” of the method (*e.g.*, a virtual probe array) is merely data (a layout) and is not equivalent to physical

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transformation. The claims do not recite tangible expression (*i.e.*, real-world result) of “producing” a probe array.

The method also does not produce a useful result (*see* the rejection for lack of patentable utility below). Thus, the method does not recite steps of producing something that is concrete, useful, and tangible, and is not statutory.

### ***Lack of Utility***

Claims 1, 4-17, 19-31, 33-35, and 84-88 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

#### ***Rejection of new claims 85-88***

Claim 85 is directed to a method for providing custom probe array comprising receiving probe set identifiers from a first and second user and producing a probe array having the first and second probe sets on the array. The specification discloses that the method may be used, for example, for detecting what genes are expressed in particular organs, tissues, species and are associated with a disease or for detecting mutations relevant to genetic diseases, see paragraph [0003]. However, the disclosed utility is not applicable to the instant claims because the instant method recites that a vendor receives a number of random probe set identifiers and an array is produced from those random probes and does not recite any genes, organs, tissue, disease, or species and/or correlation between the probes and a disease, disorder, trait, or a condition to be diagnosed. Further, the asserted utility is not specific with regard to the claimed invention. See MPEP § 2107.02. I. Although the claimed invention MAY have a substantial utility (probe arrays are generally useful), the invention does not have a specific utility. Specifically, the result

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of the claimed method is a probe array which is determined on the basis of unknown probe set identifiers. In order for the result to be used for diagnostic purposes, one skilled in the art must be aware of a correlation between the information received from the method and a disease, disorder, trait, or condition to be diagnosed. Absent any disclosure about, for example, the connection of the array to a particular state, disease, trait, *etc.*, the asserted utility is not specific. No such information is recited in the instant claims. For the reasons set forth above, the invention recited in claims 85-88 lacks a specific utility, and therefore lacks a patentable utility.

*Answer to Arguments with regard to the rejection of claims 1-2, 4-17, 19-31, 33-35, and 84 for lack of patentable utility*

Claims 1-2, 4-17, 19-31, 33-35, and 84 were rejected in the previous office action for lack of patentable utility. Applicants argue (1) that the utility does not need to be commensurate with the scope of the claims. Applicants further argue (2) that the examiner mistakenly required that the utility be stated in claims. Applicants also argue (3) that probe arrays clearly have utility because hundreds of patents have been issued claiming arrays and hundreds of million dollars per year have been spent on arrays.

In response to the *first* argument, it is noted that the asserted utility must be specific and substantial with regard to the claimed invention (must be achieved by the claimed invention) (*i.e.*, utility is commensurate with the claims). *See* MPEP § 2107.02. I.

With regard to the *second* argument, applicants misread the examiner's rejection because the examiner did not require that the asserted utility be recited in the instant claims. The examiner stated that the asserted utility (*e.g.*, detecting what genes are expressed in particular

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organs, tissues, species and are associated with a disease) was not commensurate with the instant claims and further explained why (*i.e.*, because claim 1 recites that a user selects a number of random probe set identifiers and receives from a vendor a probe array comprising probes identified by the probe set identifiers, and the asserted utility cannot be achieved with the claimed invention because the instant claims do not recite any genes, organs, tissue, disease, or species, *etc.*, and/or correlation between the probes and a disease, disorder, trait, or a condition to be diagnosed). The examiner continued and explained why the asserted utility was not specific and substantial with regard to the claimed invention (*i.e.*, because one skilled in the art must be aware of a correlation between the information received from the method and a disease, disorder, trait, or condition to be diagnosed; absent any disclosure about, for example, the connection of the array to a particular state, disease, trait, *etc.*, the asserted utility is not specific).

With regard to the *third* argument, it is noted that each application is examined individually and the fact that hundreds of patents have been issued for and millions of dollars have been spent on probe arrays does not have bearing on the examination of a particular application for a probe array. The examiner reiterates that although the claimed invention MAY have a substantial utility (probe arrays are generally useful), the invention does not have a specific utility for the reasons stated in the previous office actions, and therefore lacks patentable utility.

Thus, for the reasons stated above and in the previous office actions, the examiner maintains that the instant invention does not have a patentable utility.

***Claim Rejections - 35 USC § 112***

***Enablement***

Claims 1, 4-17, 19-31, 33-35, and 84-88 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

***Second Paragraph***

Claims 5-9 and 11-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claim 5, as amended, recites in line 1 on page 4 the limitation “a third selection from the first user.” It is not clear what “*third* selection from the *first* user” is intended because the claim only recites “a *first* selection from a *first* user” and does not recite “a *second*” selection from the *first* user. As the intended limitation is not clear, claims 5-9 and 11-16 are indefinite.

Claim 12, as amended, recites in line 3 the limitation “a fourth selection ... from the first user.” It is not clear what “fourth selection from the first user is intended” because claim 12 depends from claim 5, which only recites two selections from the first user (see claim 5, lines 2 on page 3 and line 1 on page 4). As the intended limitation is not clear, claim 12 is indefinite.

Claims 6 and 20, as amended, recite the limitation “the first and second probe sets are received over the Internet.” Claims 6 and 20 depend from claim 5 and 19, which only recite

“receiving” a first set from a first user. Claims 5 and 19 do not recite “receiving” a second probe set from a second user, but only recites “identifying a second set ... selected by an additional [e.g., second] user.” “Identifying” does not necessarily include a step of “receiving” because a second probe set may be selected and received earlier and stored in a vendor’s database, and therefore the method may only comprise “identifying” already received probes. Therefore, it is not clear whether “identifying” a second set recited in claims 5 and 19 comprises an active step of “receiving” a second set. It is also unclear what limitation of the method is intended by reciting “receiving” a second probe set, if the method does not comprise an active, positive step of “receiving”. As the intended limitation is not clear, claims 5-9, 11-16, 19-23, and 25-30 are indefinite.

Claims 1, 5, 19, 33, and 84, as amended, recite the limitation “a shared custom probe array design.” It is not clear between (or with) what or whom the array design is shared. It is also unclear what limitation of design and/or array is intended by limiting it to be “shared”. As the intended limitation is not clear, claims 1-2, 4-9, 11-16, 19-23, 25-30, 33-35, and 84 are indefinite.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 85-88 are rejected under 35 U.S.C. 102(e) as being anticipated by Kincaid, US 2003/0162183.

*Rejection of new claims 85-88.*

Kincaid discloses a method for providing a customer probe array comprising steps of receiving from a first user a first set of probe identifiers and from a second user a second set of probe identifiers ([0005], [0050], [0065]). Specifically, Kincaid discloses storing selected array design parameters from multiple commercial array clients for subsequent use, by a commercial array vendor, for preparing completed array design and/or fabricating arrays according to selected array parameters [0005], [0050]. Kincaid further discloses databases comprising in whole or in part, proprietary databases created by a commercial array vendor for use by the vendor's array customers [0048]-[0050]. Kincaid also discloses that a vendor provides additional array design parameters (*e.g.*, probe sequences from a database of array clients) that are not provided by a user and creates a complete array design [0050], [0060]-[0065]. Thus, Kincaid anticipates claim 85. Kincaid discloses a database comprising selections by previous users and selecting by a current use (*i.e.*, selecting a second set of probes after review of the first probe set by a second user) [0048]-[0050], [0060]-[0065], thereby anticipating claim 86. Kincaid discloses communicating over the Internet [0047], thereby anticipating claim 87. Kincaid discloses a nucleic acid array (fig. 2-3; [0052]), thereby anticipating claim 88.

***Claim Rejections - 35 USC § 103***

Claims 1-2, 4-9, 11-16, 19-23, 25-30, 33-35, and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson, WO 01/80155, in view of Kincaid, US 2003/0162183.

*Answer to Arguments*

The instant claims were rejected in the previous office action over Anderson and Kincaid. Applicants argue that Kincaid does not disclose sharing an array design between multiple users.

In response to the argument, it is noted that the claims do not recite “sharing an array design between multiple users.” In fact, it is not clear between (or with) what or whom the array design is “shared” (*see* the rejection under 35 U.S.C. 112, second paragraph).

It is further noted that Kincaid discloses receiving a first selection from a user, identifying a second set of probe set identifiers selected by a second user, and generating a shared array [0005], [0048]-[0050], [0060]-[0065]. Specifically, Kincaid discloses storing selected array design parameters from commercial array clients for subsequent use, by a commercial array vendor, for preparing completed array design and/or fabricating arrays according to selected array parameters [0050]. Kincaid further discloses databases comprising in whole or in part, proprietary databases created by a commercial array vendor for use by vendor’s array customers [0050]. Kincaid also discloses that a user selects array design parameters (*e.g.*, from a vendor’s database) and provides the parameters to a vendor. The vendor further supplies additional parameters which were not supplied by the user (*e.g.*, probe information from an exclusive vendor database accessible only by the vendor) and creates a complete array [0060]-[0065]. Thus, Kincaid discloses generating “a shared” array, and therefore the rejection is also maintained.

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Claims 1, 5-8, 11-13, 15-16, 19-22, 25-27, 29-30, 33-35, and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takegawa, WO 02/61646, in view of Kincaid, US 2003/0162183.

The instant claims were previously rejected. Applicants do not specifically address the rejection made over this combination of the references. The examiner maintains that Takegawa and Kincaid make claims 1, 5-8, 11-13, 15-16, 19-22, 25-27, 29-30, 33-35, and 84 obvious, and therefore also maintains the instant rejection.

Claims 2, 4, 14, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tekagawa, WO 02/61646, in view of Kincaid, US 2003/0162183, as applied to claims 1, 5-8, 11-13, 15-16, 19-22, 25-27, 29-30, 33-35, and 84 above, and further in view of Cantor, U.S. Patent 6,007,987.

The instant claims were previously rejected. Applicants do not specifically address the combination of the references. The examiner maintains that Takegawa, Kincaid, and Cantor make claims 1-2, 4-8, 11-16, 19-22, 25-30, 33-35, and 84 obvious, and therefore also maintains the instant rejection.

Claims 9 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tekagawa, WO 02/61646, in view of Kincaid, US 2003/0162183, as applied to claims 1, 5-8, 11-13, 15-16, 19-22, 25-27, 29-30, 33-35, and 84, and further in view of Garner, U.S. 2003/0033290.

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The instant claims were previously rejected. Applicants do not specifically address the combination of the references. The examiner maintains that Takegawa, Kincaid, and Garner make claims 1, 5-9, 11-13, 15-16, 19-23, 25-27, 29-30, 33-35, and 84 obvious, and therefore also maintains the instant rejection.

### ***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Miller whose telephone number is (571)272-6101. The examiner can normally be reached on 8-6, M-Thu.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, Ph. D. can be reached on (571)272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Marina Miller  
Examiner  
Art Unit 1631

MARJORIE A. MORAN  
PRIMARY EXAMINER

*Marjorie A. Moran*

12/7/06

MM